DEC 22 2009

K092186

510(k) Summary – VPAP Tx

Date Prepared	15 JULY 2009
Official Contact	Steven Lubke Director Regulatory Affairs ResMed Ltd 1 Elizabeth Macarthur Drive Bella Vista, NSW 2153 Australia Tel: +61 (2) 8884 1000 Fax: +61 (2) 8884 2000
Classification Reference	21 CFR 868.5895
Product Code	73 MNS
Common/Usual Name	Ventilator, continuous, non-life-supporting
Proprietary Name	VPAP Tx
Predicate Device(s)	VPAP Adapt (K051364) - Primary V8 (VPAP ST) (K080131) - Secondary VPAP III ST-A (K033276) - Secondary AutoSet Clinical (K952429) - Secondary
Reason for submission	New Device

Indication for Use

The VPAP Tx is indicated for the treatment of patients weighing more than 66 lb (> 30 kg) with obstructive sleep apnea (OSA), respiratory insufficiency, central or mixed apneas, or periodic breathing.

The VPAP Tx is intended to be used in a clinical environment.

Device Description

The VPAP Tx is similar to the predicate devices, VPAP Adapt (K051364), VPAP ST (K080131), VPAP III ST-A (K033276) and AutoSet Clinical (K952429). The VPAP Tx provides CPAP, Auto-titrating, Bilevel, VAuto and ASV modes to treat OSA and/or respiratory insufficiency in patients weighing more than 66 lb. This is achieved through the use of a micro-processor controlled blower system that generates airway pressures as required to maintain an "air splint" for effective treatment of OSA and/or respiratory insufficiency.

The VPAP Tx system comprises the flow generator, patient tubing, mask (patient interface) and optional HumidAire 2i humidifier.

The performance and functional characteristics of the VPAP Tx includes all the clinician and user friendly features of the predicate devices, VPAP Adapt (K051364), VPAP ST (K080131), VPAP III ST-A (K033276) and AutoSet Clinical (K952429).

Substantial Equivalence

The new device has the following similarities to the previously cleared predicate devices.

- Similar intended use
- Similar operating principle
- Similar technologies
- Similar manufacturing process

The materials used in the air path are either predicate materials (previously cleared for the same intended use) or have been tested and found compliant with the biocompatibility requirements.

Design and Verification activities were performed on the VPAP Tx as a result of the risk analysis and design requirements. All tests confirmed the product met the predetermined acceptance criteria. ResMed has determined that the new device is Substantially Equivalent to the predicate devices. The new device complies with the applicable standards and requirements referenced in the FDA guidance documents:

- FDA Draft Reviewer Guidance for Ventilators (July 1995)
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)
- FDA Off-the-Shelf Software Use in Medical Devices (September 9,1999)

Conclusion

The VPAP Tx is substantially equivalent to the previously cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 22 2009

ResMed Limited
C/O Mr. David D'Cruz
Vice President, Clinical & Regulatory Affairs
ResMed Corporation
9001 Spectrum Center Boulevard
San Diego, California 92123

Re: K092186
Trade/Device Name: VPAP Tx
Regulation Number: 21 CFR 868.5895
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: MNS
Dated: December 8, 2009
Received: December 10, 2009

Dear Mr. D'Cruz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K092186

Device Name: VPAP Tx

Indication for Use

The VPAP Tx is indicated for the treatment of patients weighing more than 66 lb (> 30 kg) with obstructive sleep apnea (OSA), respiratory insufficiency, central or mixed apneas, or periodic breathing.

The VPAP Tx is intended to be used in a clinical environment.

L Schulte

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092186

Prescription Use ___X___ AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)